

We Claim:

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1. A method of retaining a medical implant within a body cavity, the method
5 comprising the steps of:
 providing a medical implant;
 forming a tissue pocket on a wall of a body cavity, said tissue pocket having a first
opening exposed to the interior of the body cavity; and
 retaining at least a portion of the medical implant within the tissue pocket.
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2. The method according to claim 1, wherein the forming step includes the step of
attaching regions of body tissue on the wall of the body cavity.
3. The method according to claim 1 wherein the method includes forming the tissue
15 pocket and then inserting the portion of the medical implant into the tissue pocket.
4. The method according to claim 1 wherein the method includes placing the portion
of the medical implant into contact with the wall and forming the tissue pocket around the
portion of the medical implant.
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5. The method according to claim 1 wherein:
 the tissue pocket includes a second opening;
 the retaining step includes positioning the medical implant such that a first portion
of the medical implant extends from the first opening and a second portion of the medical
25 implant extends from the second opening; and
 the second portion of the medical implant includes a retention element
proportioned to resist passage of the retention element through the second opening during
the retaining step.
- 30 6. The method according to claim 5 wherein the positioning step includes expanding
the retention element to prevent release of the medical implant from the tissue pocket.

7. The method according to claim 6 wherein the expanding step includes inflating the retention element.
8. The method according to claim 5 wherein the positioning step includes deforming the retention element to prevent release of the medical implant from the tissue pocket.
9. The method according to claim 5 wherein:
the method provides the medical implant to include a leg member retainable within the tissue pocket, wherein the retention element is positioned on the leg member.
10. The method according to claim 5 wherein the retention element is a clip and the positioning step positions the clip to extend through the first and second openings.
11. The method according to claim 1 wherein the medical implant is retained within the tissue pocket without the use of a fastener that both physically penetrates body tissue and is physically connected to the medical implant.
12. The method of claim 2, further including the step of causing the attached regions of tissue to adhere to one another .
13. The method according to claim 2 wherein the body cavity is a stomach having an interior and an exterior, and wherein the attaching step attaches regions of tissue such that serosal tissue from a first region and serosal tissue from a second region are in contact with one another.
14. The method according to claim 13, further including the step of causing the attached regions of serosal tissue to adhere to one together to form a tissue adhesion.
15. The method according to claim 2 wherein the body cavity is a stomach having an interior and an exterior, and wherein the attaching step attaches interior regions of tissue.

16. The method according to claim 15 wherein the attached interior regions of tissue comprise mucosal tissue.
17. The method according to claim 1, wherein the body cavity is a stomach and the method forms the tissue pocket accessible from the stomach interior.
18. The method according to claim 2, wherein the body cavity is a stomach and the regions of body tissue are on the exterior surface of the stomach.
19. The method according to claim 18 wherein the attaching step includes attaching the regions to form a fully-enclosed tissue pocket, and forming the at least one opening in the tissue pocket.
20. The method according to claim 18 wherein:
the method includes drawing exterior stomach tissue into apposition to form a tissue fold;
the method includes forming a cut in the tissue fold to create a window therein;
and
the attaching step includes attaching opposed layers of tissue surrounding the window, wherein the tissue pocket extends between the opposed layers of tissue bordered by the cut.
21. The method according to claim 18, wherein:
the method includes drawing exterior stomach tissue into apposition to form a stomach fold;
the attaching step includes forming a hole extending through the stomach fold and attaching opposed layers of tissue in the region surrounding the hole; and
the tissue pocket comprises the hole extending through the opposed layers of tissue.
22. The method according to claim 2 wherein the attaching step attaches the regions of body tissue together using suture.

23. The method according to claim 2 wherein the attaching step attaches the regions of body tissue together using staples.
- 5 24. The method according to claim 2 wherein the attaching step attaches the regions of body tissue together using clips.
25. The method according to claim 2 wherein the attaching step attaches the regions of body tissue together using adhesives.
- 10 26. The method according to claim 2 wherein the method includes modifying at least one of the regions of body tissue prior to attaching the regions into contact with one another.
- 15 27. The method of claim 26 wherein the modifying step includes ablating at least one of the regions of body tissue.
28. The method of claim 26 wherein the modifying step includes cutting at least one of the spaced apart regions of body tissue.
- 20 29. The method of claim 28 wherein the cutting step includes shaving a tissue layer from at least one of the regions of body tissue.
30. The method according to claim 26 further including the step of causing the regions of body tissue to adhere to one another.
- 25 31. The method according to claim 26 wherein at least one of the regions of body tissue is mucosal tissue, and wherein the modifying step includes removing a portion of the mucosal tissue to expose underlying tissue layers.
- 30 32. The method according to claim 31 wherein the modifying step exposes a submucosal tissue layer.

33. The method according to claim 31 wherein the modifying step exposes a serosal tissue layer.
- 5 34. The method according to claim 31 wherein the modifying step exposes a muscularis tissue layer.
35. The method according to claim 1 wherein the medical implant is a drug delivery device.
- 10 36. The method according to claim 1 wherein the medical implant is a diagnostic device.
37. The method according to claim 1 wherein the medical implant is an anti-reflux device.
- 15 38. The method according to claim 1 wherein the body cavity is the stomach and wherein the medical implant is a device for inducing weight loss.
- 20 39. The method according to claim 38, wherein the medical implant is an expandable space-occupier and wherein the method includes expanding the space-occupier within the stomach to decrease the effective volume of the stomach.
40. The method according to claim 38, wherein the medical implant is a flow-
- 25 restrictive device and wherein the method includes positioning the flow-restrictive device to restrict the rate of flow of food into the stomach.
41. The method according to claim 1, further including the step of retaining the medical implant using a plurality of tissue pockets formed in the body cavity.
- 30 42. The method according to claim 41 wherein the medical implant includes a plurality of leg members, and wherein the method includes the step of forming a plurality

of tissue pockets in the body cavity and retaining the leg members within the tissue pockets.

43. The method according to claim 1 wherein the body cavity is a stomach and
5 wherein the tissue pocket is formed using instruments passed into the stomach through the esophagus.

44. The method according to claim 43 wherein the body cavity is a stomach and
wherein the tissue pocket is formed only using instruments passed into the stomach
10 through the esophagus.

45. The method according to claim 1 wherein the body cavity is a stomach and
wherein the tissue pocket is formed using instruments passed through the abdominal wall.

15 46. An obesity-controlling apparatus retainable in at least one tissue pocket formed on a wall of a human stomach, the apparatus comprising:

a member proportioned to be retained within a tissue pocket formed on a wall of a human stomach; and

a weight-loss component attached to the member.

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47. The apparatus according to claim 46 wherein the weight-loss component includes a restrictive device proportioned to effectively narrow a passage from the esophagus into the stomach to thereby restrict the rate at which food flows into the stomach.

25 48. The apparatus according to claim 46 wherein the weight-loss component includes an expandable space-occupier device proportioned to reduce the effective volume of the stomach.

49. The apparatus according to claim 46 wherein the weight-loss component includes
30 a drug-eluting device containing a hunger-controlling agent.

50. The apparatus according to claim 46 wherein the member is retainable within the tissue pocket in the absence of a fastener attached to the apparatus that physically penetrates body tissue.
- 5 51. The apparatus according to claim 46 wherein apparatus is positionable in a human stomach in which tissue pockets have been formed to include first and second openings, and wherein the member includes a retention element proportioned to prevent movement of the retention element through the second opening to prevent release of the member from the tissue pocket.
- 10 52. The apparatus according to claim 51 wherein the retention element is expandable to prevent release of the member from the tissue pocket.
53. The apparatus according to claim 52 wherein the retention element is inflatable.
- 15 54. The apparatus according to claim 52 wherein the retention element is compressible to a reduced-diameter position.
55. The apparatus according to claim 51 wherein the retention element is deformable to prevent release of the member from the tissue pocket.
- 20 56. The apparatus according to claim 51 wherein the retention element is a clip extendable through first and second openings of a tissue pocket.
- 25 57. The apparatus according to claim 47 wherein the restrictive device is a ring.
58. The apparatus according to claim 47 wherein the restrictive device is a mesh screen.
- 30 59. The apparatus according to claim 47 wherein the restrictive device is an inflatable balloon.

60. The apparatus according to claim 47 wherein the restrictive device is a pouch.
61. The apparatus according to claim 46, including a plurality of said members
proportioned to be retained within a tissue pocket formed by attaching tissue surfaces of a
5 human stomach.
62. The apparatus according to claim 46 including at least three of said members.
63. A medical implant system, comprising:
10 an instrument insertable into a body for attaching regions of body tissue on the
wall of a body cavity to form a tissue pocket; and
a medical implant positionable within the body cavity, the medical implant
including at least one portion proportioned for retention within a tissue pocket formed in
the body cavity.
- 15 64. The implant system according to claim 63 wherein the medical implant is a drug
delivery device.
65. The implant system according to claim 63 wherein the medical implant is a
20 diagnostic device.
66. The implant system according to claim 63 wherein the medical implant is an anti-
reflux device.
- 25 67. The implant system according to claim 63 wherein the medical implant is
positionable within a stomach for inducing weight loss.
68. The implant system according to claim 63, wherein the medical implant is an
expandable space-occupier positionable within a stomach to decrease the effective
30 volume of the stomach.

69. The implant system according to claim 63, wherein the medical implant is a flow-restrictive device positionable within a stomach to restrict the rate of flow of food into the stomach.

5 70. The implant system according to claim 63 wherein the instrument is a suturing instrument.

71. The implant system according to claim 63 wherein the instrument is a stapling instrument.

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72. The implant system according to claim 63 wherein the instrument is a clip-applier.

73. The implant system according to claim 63 wherein the medical implant includes a plurality of leg members proportioned to be retained within a plurality of tissue pockets
15 formed using the instrument.

74. The implant system according to claim 63 wherein the medical implant is retainable within the tissue pocket without the use of a fastener that both physically penetrates body tissue and is physically connected to the medical implant.

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75. A method of retaining a medical implant within a body cavity having a wall, comprising the steps of:
positioning at least a portion of a medical implant within a body cavity; and
re-shaping a wall of the body cavity such that the re-shaped wall prevents
25 migration of the medical implant out of the body cavity.

76. The method according to claim 75 wherein the re-shaped wall prevents migration of the medical implant in the absence of a fastener attached to the medical implant and physically penetrating tissue of the wall.

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77. The method according to claim 75 wherein the positioning step is carried out prior to the re-shaping step.

78. The method according to claim 75 wherein the positioning step is carried out after the re-shaping step.
- 5 79. The method according to claim 75 wherein the re-shaping step includes forming a tissue pocket on the wall, wherein at least a portion of the medical implant is retained within the tissue pocket.
80. The method according to claim 75 wherein the re-shaping step includes the step of
10 positioning a re-shaping implant in contact with the wall.
81. The method according to claim 80 wherein the re-shaping step includes the step of positioning the re-shaping implant in contact with an exterior surface of the wall.
- 15 82. The method according to claim 80 wherein the re-shaping step includes the step of positioning the re-shaping device in contact with an interior surface of the wall.
83. The method according to claim 80 wherein the re-shaping step includes positioning a circumferential band in contact with the wall.
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84. The method according to claim 83 wherein the body cavity is a stomach, and wherein the re-shaping step further includes the step of positioning a re-shaping liner on an interior surface of the stomach wall.
- 25 85. The method according to claim 84 wherein the liner includes a neck portion, and wherein the re-shaping step further includes positioning the circumferential band in contact with the wall such that wall tissue is disposed between the neck portion and the liner.
- 30 86. The method according to claim 75 wherein the re-shaping step includes attaching regions of tissue together.

87. The method according to claim 86 wherein the attaching step forms a tunnel and wherein the method includes positioning at least a portion of the implant within the tunnel.
- 5 88. The method according to claim 87 wherein the implant includes an expandable portion and wherein the positioning step includes positioning the expandable portion into contact with tissue surrounding the tunnel.
89. The method according to claim 87 wherein the body cavity is a stomach and the
10 attaching step forms a tunnel in the proximal stomach, wherein the tunnel is at least partially contiguous with the esophagus.
90. The method according to claim 85 wherein the attaching step forms a barrier proportioned to obstruct passage of the implant from one region of the body cavity into
15 another region of the body cavity.
91. The method according to claim 90 wherein the body cavity is a stomach, and wherein the barrier prevents migration of the implant towards the intestinal tract.
- 20 92. The method according claim 91 wherein the barrier is formed in the proximal portion of the stomach and the positioning step positions the implant between the barrier and the esophagus.
93. The method according to claim 74 wherein the medical implant is an obstructive
25 device positionable within a stomach.
94. The method according to claim 74 wherein the medical implant is a restrictive device positionable within a stomach.
- 30 95. The method according to claim 74 wherein the medical implant is an anti-reflux device positionable within a stomach.

96. The method according to claim 74 wherein the medical implant is a drug-eluting device.
97. The method according to claim 75 wherein the medical implant is a diagnostic device.
98. The method according to claim 74 wherein the medical implant is a therapeutic device.
99. The method according to claim 19, further including the step of forming a second opening in the tissue pouch.
100. The method according to claim 1 wherein the retaining step retains the entire medical implant within the pocket.
101. The method according to claim 100, further including the step of closing the opening after positioning the medical implant within the pocket.
102. A method of attaching a medical implant to stomach tissue, including the steps of:
positioning a medical implant within stomach having a wall; and
attaching the medical implant to an external reinforcement device positioned in contact with the exterior surface of the wall using a connector extending through the wall from the implant to the external reinforcement device.
103. The method according to claim 102 wherein the external reinforcement device is a pledget.
104. The method according to claim 102 wherein the external reinforcement device is a t-bar.
105. The method according to claim 102 wherein the external reinforcement device is a band.

106. The method according to claim 102 wherein the external reinforcement device is a patch of reinforcing material.
- 5 107. A method of positioning an implant within the stomach, comprising the steps of:
forming a plurality of plications in a wall of a stomach to form at least one tissue ridge;
and positioning an implant in contact with the tissue ridge.
- 10 108. The method according to claim 107 wherein the forming step includes the step of attaching regions of body tissue on the wall of the stomach.
109. The method according to claim 108 wherein the attaching step is performed using sutures.
- 15 110. The method according to claim 108 wherein the attaching step is performed using t-bars.
111. The method according to claim 108 wherein the attaching step is performed using pledgets.
- 20 112. The method according to claim 108, wherein attaching step causes sections of serosal tissue to be positioned in apposition, and wherein the method further includes the step of causing the opposed sections of serosal tissue to adhere to one another.
- 25 113. The method according to claim 112 wherein the causing step is performed prior to the positioning step.
114. The method according to claim 107, wherein the positioning step includes
- 30 fastening the implant to the tissue ridge.

115. The method according to claim 107 wherein the forming step is performed using endoscopic instruments passed through the esophagus into the stomach.

116. The method according to claim 115 wherein the forming step includes the steps
5 of:

extending a tissue-engaging device through the esophagus into the stomach;
engaging tissue with the tissue-engaging device and drawing the engaged tissue in
a proximal direction to form a plication; and
during the drawing step, advancing a fastener through the plication.

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117. The method according to claim 107 wherein the positioning step includes the steps
of:

extending tissue-engaging members through the esophagus into the stomach;
engaging portions of the tissue ridge with the elements and drawing the engaged
15 portions in a proximal direction; and
during the engaging step, advancing the implant against the tissue ridge.

118. The method according to claim 117 wherein the tissue-engaging members
including a plurality of elongate members having tissue-engaging distal ends, and
20 wherein the advancing step includes slidably attaching the implant to the elongate
members and sliding the implant along the members in a distal direction.

119. The method according to claim 107 wherein the implant is an obesity-controlling
implant.

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120. The method according to claim 107, further including the step of attaching a
restrictive component to the implant, the restrictive component having an opening
oriented such that food ingested by the patient flows through the opening and into the
stomach, the opening proportioned such food flows through the opening at a rate that is
30 slower than the rate at which food would flow into the stomach in the absence of the
restrictive component.

121. The method according to claim 120, wherein the restrictive component is a first restrictive component, and wherein the method further included the step of removing the first restrictive component and attaching a second restrictive component, the second restrictive component having an opening proportioned such food flows through the opening at a rate that is different than the rate at which food would flow into the stomach through the opening of the first restrictive component.

122. The method according to claim 107 wherein the implant is a device for controlling gastro-intestinal reflux disease.

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123. The method according to claim 1 wherein the step of forming a tissue pocket comprises the steps of:

forming a line of attachment between opposed stomach wall regions to form the tissue pocket;

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forming a second line of attachment spaced apart from the first line;

forming an opening through each of the opposed stomach walls at a location between the first and second lines, said opening bounded by at least four cut tissue edges; and

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causing the cut tissue edges to heal, creating a seal between the opposed stomach wall regions.

124. The method according to claim 123 wherein the first and second lines are substantially straight.

25 125. The method according to claim 124 wherein the first and second lines form a circular pattern and wherein the opening is formed within the circular pattern.

126. The method according to claim 123 wherein at least one of the first and second lines is non-straight.

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127. The method according to claim 123 wherein the steps of forming the first and second lines include laparoscopically introducing a tissue fastening device and forming the lines using the fastening device.

5 128. The method according to claim 127 wherein the step of forming the opening is formed using the tissue fastening device.

129. The method according to claim 128 wherein the steps of forming the first and second lines and the step of forming the opening are performed substantially
10 simultaneously.

130. A kit comprising:
a medical implant deployable within a stomach; and
instructions for use describing an implantation method comprising the steps of:
15 forming a tissue pocket on a wall of the stomach, said tissue pocket
having a first opening exposed to the interior of the stomach; and
retaining at least a portion of the medical implant within the tissue
pocket.

20 131. The kit according to claim 130, further including a laparoscopic cutting and fastening instrument, wherein the instructions for use describe forming the tissue pocket using the laparoscopic cutting and fastening instrument.

132. The kit according to claim 130 wherein the medical implant is a implant for
25 inducting weight loss.

133. The kit according to claim 132 wherein the medical implant is proportioned to slow the flow of ingested food from the esophagus into the stomach.

30 134. The kit according to claim 133 wherein the medical implant is an obstructive device.

135. The kit according to claim 133 wherein the medical implant is a restrictive device.

136. A kit comprising:

a medical implant deployable within a stomach; and

5 instructions for use describing at least one of the methods according to Claims 1-45, 75-101, and 102 – 129.137. A method of forming a plication in stomach tissue, comprising the steps of:

positioning a patch between opposed layers of body tissue; and

causing an adhesion to form through the patch between the opposed layers.

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138. The method of claim 137, wherein the tissue layers are serosal layers.

139. The method of claim 137, wherein the tissue layers are mucosal layers.

15 140. The method of claim 137, wherein the method is further for retaining an implant within the stomach, and wherein the method includes coupling a portion of the implant to the patch.

20 141. The method of claim 137, wherein the patch includes an extension element and wherein the positioning step causes the extension element to protrude into the stomach interior.

25 142. The method of claim 141, wherein the method is further for retaining an implant within the stomach, and wherein the method includes coupling the implant to the extension element.

143. The method of claim 142, wherein the extension element comprises a loop, and wherein the method includes passing a portion of the medical device through the loop.

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144. The method of claim 137, wherein the plication forms a pocket between a portion of the tissue layers, and wherein the method includes causing a portion of the patch to line the pocket.

5 145. The method of claim 137, wherein the method is further for position an implant within the stomach, and wherein the method includes the step of positioning an implant in contact with the plication.

10 146. A medical implant system, comprising:
an instrument insertable into a body for attaching regions of body tissue on the wall of a body cavity to form a plication; and
patch positionable between the regions of body tissue; and
retaining means for retaining the plication at least until an adhesion forms between the regions of body tissue.

15 147. The medical implant system of claim 146, further including
a medical implant positionable within the body cavity and configured to be retained within the body cavity by the plication.

20 148. The implant system according to claim 147, wherein the medical implant is a drug delivery device.

25 149. The implant system according to claim 147, wherein the medical implant is a diagnostic device.

150. The implant system according to claim 147, wherein the medical implant is an anti-reflux device.

30 151. The implant system according to claim 147, wherein the medical implant is positionable within a stomach for inducing weight loss.

152. The implant system according to claim 147, wherein the medical implant is an expandable space-occupier positionable within a stomach to decrease the effective volume of the stomach.

5 153. The implant system according to claim 147, wherein the medical implant is a flow-restrictive device positionable within a stomach to restrict the rate of flow of food into the stomach.

10 154. The implant system according to claim 146, wherein the instrument is a suturing instrument.

 155. The implant system according to claim 146, wherein the instrument is a stapling instrument.

15 156. The implant system according to claim 146, wherein the instrument is a clip-applier.

 157. The implant system according to claim 146, wherein the retaining means is selected from the group consisting of sutures, staples, clips, fasteners, t-bars, pledgets,
20 adhesives and studs.